Claims 20-23 were rejected under 35 USC § 103 as being obvious over Callahan et al., Finkenaur, Reissman et al. and Moore, taken with Sauerbier et al. This rejection is traversed for the following reasons.

Callahan (US 4,908,475) teaches solubilization of a linear peptide in approximately 100-10,000 parts by weight of acetic acid followed by lyophilization. Then the crude peptide was purified by gel filtration in order to get the purified, linear peptide. Callahan describes a synthesis and a purification process of new compounds with vasopressin antagonistic activity, but not a pharmaceutical process to produce a sterile lyophilisate of an LH-RH antagonist for medical use. Callahan teaches gel filtration but not a sterile filtration. The gel filtration process is not suitable for producing a sterile lyophilisate. It is a method for fractionation of substances according to their molecular size. Thus, the Callahan reference would not lead a person of skill in the art to the present invention.

The Finkenauer patent discloses a stable composition comprising a polypeptide growth factor and a water soluble, swellable, pharmaceutically acceptable polymer capable of imparting viscosity to a reconstituted solution of the composition. The presence of the bulking agent mannitol is only named in connection with a composition containing a gel forming preparation. It is respectfully submitted that a

decapeptide such as Cetrorelix cannot be compared with a polypeptide, the physicochemical properties being very different. A person of skill in the art would not glean any information from Finkenauer as to how to make a sterile lyophilisate of the decapeptide Cetrorelix.

Reissmann shows in a scientific, pharmacological article the effect of Cetrorelix acetate or trifluoroacetate on DMBA induced mammary carcinoma. A medically usable, sterile, lyophilized Cetrorelix is not described.

Thus, none of these references discloses the sterile lyophilisate of a peptide.

The Sauerbeir patent (U.S. 5,204,335) is quite removed from the present invention. In this patent only an Ifosfamide lyophilisate with hexitol is disclosed. Ifosfamide is not a peptide, and does not have the specific physicochemical properties of a gel-forming peptide. Thus, a person of skill in the art would not have been motivated to combine this reference with any of the other cited references in order to achieve the presently claimed invention.

For all of the above reasons, it is submitted that the presently claimed invention is not obvious from the cited references, either alone, or in combination. Withdrawal of the 35 USC § 103 rejection is respectfully requested.

All rejections having been addressed, it is respectfully submitted that this application is in condition for allowance,

and Notice to that effect is respectfully requested.

Respectfully submitted,

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